

R E M A R K S

Claims 1-11, 13-22, and 24-26 are in the application. Claim 24 has been withdrawn as being drawn to a non-elected invention. In the Office Action, Claim 2 was rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claims 2-5, 7, 15-19, and 16 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description and enablement requirements. Claim 21 was rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claims 2, 14, 16, and 17 were objected to for various grammatical errors.

By the present amendments, Claims 2, 4, 14, and 21 are amended to more particularly point out and distinctly define the claimed subject matter, and to correct the noted and other minor grammatical errors. The specification is amended to comply with the rules for sequences. The Sequence Listing is amended to include sequences originally disclosed in the application, but not previously included in the Sequence Listing. As per C.F.R. 1.825, both a printed replacement section and two computer-readable copies of the sequence listing are included with this submission. Support for the amendment can be found in Fig. 2 and on pages 13-16 of the application as originally filed. The computer readable copy of the sequence listing is the same as the paper copy, and neither the paper copy nor the computer-readable copies of the sequence listing contains any new matter. In fact, no new matter is added to the case by any of the amendments.

Applicants would like to thank the Examiner for the indication that claims 1, 6, 8-11, 13, 20, 22, and 25 are allowable.

All objections and rejections are respectfully traversed. Reconsideration and favorable action are requested in light of the forgoing amendments and these remarks.

A. The Objections to Claims 2, 14, 16, and 17 are Moot.

As noted above, Claims 2, 14, 16, and 17 were objected to due to various alleged informalities and grammatical errors, and due to alleged non-compliance with the rules regarding nucleotide sequences. Claim 14 is amended, as suggested in the office action, to be in proper form, thereby overcoming the objection. It is believed that the alleged objectionable periods in claims 2, 16 and 17 resulted from a scanning error, since the original draft of the application had

commas in those positions. The claims are reproduced here as originally submitted, with commas. No new matter is added into the case by the present amendments. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objections to Claims 2, 14, 16, and 17, and prompt allowance thereof.

B. Claim 2 is Definite.

As also noted above, Claim 2 was rejected as allegedly indefinite because the sequence claimed was said to be unclear. However, Claim 2 is amended to specify that the nucleotide sequence being modified by the claimed process is SEQ ID NO:3. Accordingly, the claim is believed to now be in fully compliant with the sequence rules. Reconsideration and allowance of Claim 2 are hereby respectfully requested.

C. Claims 2-5, 7, 15-19, and 26 Comply With the Written Description and Enablement Requirements.

As noted above, Claims 2-5, 7, 15-19, and 26 were rejected as allegedly failing to comply with the written description and enablement requirements of 35 U.S.C. §112. It is believed the present amendments to the claims and the specification render the claimed subject matter sufficiently clear and definite and in full compliance with §112. The specification fully describes how to optimize the native gene coding for hG-CSF, defined by SEQ ID NO:3, by making modifications to particular segments of the gene, as taught on pages 8-10 of the specification. As described in *In re Grimme* (124 USPQ 499), a single specific example can be sufficient disclosure for claiming a genus. In *In re Robbins* (166 USPQ 552), the CCPA ruled that “mention of representative compounds encompasses by generic claim language clearly is not required by §112 or any other provision of the statute.” Applicants have provided an example of how to make a particular optimized gene, Fopt5, described by SEQ ID NO:1, and it is believed a person of skill in the art could readily apply the concepts described in the specification to further optimize the native gene (SEQ ID NO:3), as claimed in Claim 2, for more efficient expression in *E. coli*, and practice the subject matter as claimed without undue experimentation. Accordingly, reconsideration and allowance of independent Claim 2, and dependent Claims 3-5, 7, 15-19, and 26 are hereby respectfully requested.

D. Claim 21 is Definite.

Finally, Claim 21 was rejected as allegedly indefinite. However, Applicants contend that the claim, as amended, is compliant with all sections of §112. Furthermore, the recited term “IPTG” is a new limitation being added in the claim, and does not need antecedent basis in claim 20. The use of IPTG for induction is taught in the specification on page 11, first full paragraph. IPTG is isopropyl β-D-1-thiogalactopyranoside, a well-known biochemical reagent. Any person of skill in the art reading the specification would know the meaning of this term and would be able to practice the claim without undue experimentation. Accordingly, reconsideration and allowance of claim 21 are hereby respectfully requested.

CONCLUSION

Applicants respectfully submit that a full and complete response to the office action is provided herein, and that the application is now fully in condition for allowance. Action in accordance therewith is respectfully requested.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 122355.

Respectfully submitted,  
LUEDEKA, NEELY, AND GRAHAM, P.C.  
By: /Mark S. Graham/

Mark S. Graham  
Registration Number 32,355  
Attorneys for Applicants<sup>1</sup>

Date: November 10, 2008

---

<sup>1</sup> The above-mentioned practitioner is acting in this matter on behalf of Applicant(s) based on communications from Corporate Intellectual Property of Novartis International AG, Basel, Switzerland, or an affiliate thereof or a successor thereto. (See Declaration and Power of Attorney on file in connection with this application.) This is without waiver of any attorney-client privilege or other protection of confidentiality, all of which are expressly reserved.

LUEDEKA, NEELY & GRAHAM, P.C.  
Attorneys at Law  
P.O. Box 1871  
Knoxville, TN 37901-1871

Phone: 865-546-4305  
Facsimile: 865-523-4478  
E-Mail: MGRAHAM@LNG-PATENT.COM

*E-Filing*